FDA OVERSIGHT HEARING ON CODEX BADLY NEEDED

The Honorable Dan Burton, Chairman
House Government Reform and Oversight Committee
c/o Milt Copulos/Beth Clay
Room 2157 RHOB
Washington, DC 20515

3670 '99 SEP 17 PM2:31

Dear Congressman Burton:

Prior to last September's meeting of the Codex Committee on Nutrition and Food for Special Dietary Use, you and four other members of Congress strongly requested in writing that the FDA's Dr. Yetley remove the second paragraph from the U.S. codex comments on agenda item #5 (vitamins and minerals), because it contradicted the first paragraph, and lent credence to the unscientific notion that "maximum upper potency limits" should be put on vitamins and minerals. Dr. Yetley not only ignored your written request, but John Hammell caught her doing so on videotape which has been put on the Life Extension Foundation's website in the political section, along with footage of John being forced to stop taping by the German Codex Chairman (http://www.lef.org). A complete account of what happened is available at http://www.iahf.com under "breaking news."

From a standpoint of safety, there is no justification for attempting to apply a "Risk Assessment" document which was designed for evaluating toxic pharmaceutical drugs, to dietary supplements, which have been well established through the National Association of Poison Control Centers, and numerous other sources to be extraordinarily safe, even when consumed in doses much higher than the RDA. Orthomolecular physicians such as Bonnie Camo, M.D. have seen doses as high as 3 grams per day of niacin used in complete safety, while the National Academy of Sciences and FDA are advocating a maximum upper potency limit of just 35 mg, just because a few highly sensitive individuals experience a tingling sensation known as the "niacin flush" when taking niacin in low doses. There is nothing unsafe about the niacin flush, which actually helps circulation and is considered pleasurable by some.

It is obvious to consumers around the world that the FDA is attempting to use the highly unscientific, and heavily prejudiced National Academy of Sciences document titled "A Risk Assessment Model for Establishing Upper Limits for Nutrients" as a means of moving beyond the consumer generated impasse at the Codex Committee on Nutrition and Foods for Special Dietary Use. The FDA has announced its intention to harmonize its regulations to emerging Codex standards in an Advance Notice of Proposed Rulemaking that was published in the Federal Register on July 7, 1997, vol. 62, #129 pp.36243-36248. You can view this at http://iahf.com/codx-fda.txt.

I urge you to call John Hammell, Bonnie Camo M.D., and other witnesses to a Hearing before your Committee, and I urge you to force the FDA to withdraw the second paragraph of its comments along with the NAS Risk Assessment document in keeping with current US Law. Congress has spoken clearly on this with the passage of DSHEA, and most recently again in October of 1997 when dietary supplements were specifically exempted from the harmonization language in the FDA Reform Bill.

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TO: DAN BURTON, CHAIRMAN
HOUSE GOVERNMENT REFORM AND OVERSIGHT COMMITTEE.

3/21/99

3671 '99 SEP 17 P12:31

DEAR CONGRESSMAN BURTON:

THE FDA CONTINUES TO LAY ITS HEAVY BUREAUCRATIC HAND ON THE DEVELOPMENT OF WAYS OF EXTENDING THE LIVES OF U.S. CITIZENS THROUGH INNOVATIVE USE OF VITAMINS AND MINERALS. AS A SENIOR CITIZEN WHO WAS GRIEVOUSLY WOUNDED DURING WWII, I DO NOT WANT TO BE DENIED USE OF, OR ACCESS TO ANY SUBSTANCE, WHICH MAY EXTEND MY LIFE AND/OR MAINTAIN ITS QUALITY.

I HAVE ABSOLUTELY NO FAITH IN THE DECISION-MAKING ROLE OF THE FDA BUREAUCRATS – EVEN THOUGH THEY MAY BE DEGREED "EXPERTS". THESE INDIVIDUALS ARE NOT IN THE FOREFRONT OF THE EXPLODING UNIVERSE OF HOW NUTRITION CAN EXTEND OUR LIVES. JUST THE OPPOSITE – THEY PORTRAY THEMSELVES AS SELF-ANOINTED GUARDIANS OF THE PUBLIC'S HEALTH. YET, ALMOST ANY M.D., CONVENTIONAL OR ALTERNATIVE, AGREES THAT AS BASIC A MEASUREMENT AS THE RDA IS GROSSLY UNDERSTATED WHEN EXAMINED IN THE LIGHT OF CURRENT NUTRITION AND DIET KNOWLEDGE.

HOW IS IT POSSIBLE THAT US CITIZENRY IS CONSTANTLY UNDER THREAT OF BEING DENIED ACCESS TO THE LATEST, NEWEST, MOST INNOVATIVE MEASURES TO EXTEND THEIR PRODUCTIVE LIVES? IS THAT THE REASON I SUFFERED THE LOSS OF USE OF MY LEGS? THE FDA IS OUT-OF-TOUCH!

THE CODEX COMMENTS ARE A VERY REAL THREAT TO THE WELL-BEING OF THE HUNDREDS OF THOUSANDS WHO HAVE BENEFITTED FROM THE ON-GOING REVOLUTION IN NUTRITION.

MILLIONS OF U.S. CITIZENS ARE ACTIVELY SEEKING TO AVAIL THEMSELVES OF THE VITAMINS, MINERALS AND OTHER SUPPLEMENTS THAT, IN THE PAST TWO DECADES, HAVE IMPROVED THE QUALITY OF LIFE AND EXTENDED THEIR USEFUL LIVES.

REMEMBER, TOO, THAT THE FDA ADVISORY BOARD HAS IN RECENT YEARS APPROVED AT LEAST A DOZEN NEW PHARMACEUTICAL PREPARATIONS WHICH HAVE LED TO THE DEATHS OF PATIENTS IN SUFFICIENT NUMBERS TO HAVE THE PRODUCT REMOVED. IN CONTRAST THE VITAMINS AND MINERALS WHICH THE FDA NOW SEEKS TO CONTROL HAVE HAD CENTURIES OF USAGE AROUND THE WORLD - VIRTUALLY ALL WITH MINIMAL OR NO SIDE EFFECTS.

SINCERELY,

Stanley J. Dudek

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